Remarks

Claims 1-20 are pending. All pending claims stand rejected by the Examiner.

The Examiner objects to the drawings for failing to contain a brief description of Figures 15A-18. Applicant amends the specification to include a brief description of Figures 15A-18. Support for the amendment can be found in the specification as a whole and, for example, paragraphs [0085] – [0087] on page 8 of the specification as published on January 6, 2005.

The Examiner objects to claims 4 and 14 because of grammatical errors. Applicant amends these claims as suggested by the Examiner. Claim 18 is objected to as having insufficient antecedent basis for the plural "segments." Accordingly, Applicant amends claim 18 to recite "segment."

Claims 15-18 stand rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant amends claim 15 to recite "the at least one electrode strand" to conform to the terminology used throughout the remainder of claims 15-18.

No new matter enters through these amendments to the specification or the claims.

Rejections under 35 U.S.C. § 102 based on Kordis

Claims 1-20

Claims 1-20 stand rejected as anticipated by Kordis. Applicant amends claim 1 to more clearly recite that the ablation catheter includes an ablating electrode.

Regarding independent claim 1, the Examiner alleges that "Kordis discloses an ablation catheter (10) comprising . . . . at least one electrode (96) arranged along the at least partial curve (Fig. 38) . . . ." (Office action at page 4). Similarly, regarding independent claim 19, Kordis allegedly discloses a "flexible electrode means for

conveying ablation energy to a target tissue . . . ." (Office action at page 7). Applicant respectfully disagrees.

Applicant concedes that the term "ablation" can be found in Kordis, but if due consideration is given to the teachings of Kordis, it is clear that Kordis cannot sustain a rejection based on anticipation. Anticipation requires the teaching of each and every element in the cited reference. Applicant submits that the electrode structure cited by the Examiner is a mapping electrode, but does not teach a device having an ablation electrode. In particular, none of the embodiments found in Kordis teaches an ablating electrode as required by Applicant's claims.

A close reading of Kordis demonstrates that the "ablation catheter" alleged by the Examiner is not the structure described in the rejection. Kordis recites its "principal objective" as "the realization of safe and efficacious endocardial mapping techniques." (Kordis at col. 2, lines, 12-13). Admittedly, Kordis does teach that a mapping electrode can be used in conjunction with an ablation electrode, but Kordis is directed to a mapping electrode—not an ablation device. Other than discussing ablation in connection with the prior art in the Background section, the term "ablation" only appears twice in the remainder of the specification:

> The helical wrapping of the ribbon cables 92 also leaves the interior bore of the catheter tube 12 open. The open interior bore can be used to conduct liquids; or to accommodate ***another probe for ablation purposes*** and the like. (Kordis at col. 14: lines 43-46 - regarding Fig. 42).
>
> With the outer sleeve 108 in place, the catheter tube 12 presents a diameter of about 8 French. And, as before described, ***the central lumen of the catheter tube 12 is left completely open to accommodate an ablation catheter*** or the like. (Kordis at col. 19: lines 51-55 - regarding Figs. 53-54).

In both instances, the ablation catheter is a separate device that *may* be combined with the mapping catheter disclosed in Kordis. Applicant's claim requires an ablating electrode subject to certain limitations. Kordis simply contains no description of an

ablating electrode and certainly not one subject to the limitations required by Applicant's claim.

One of ordinary skill would appreciate that there is a significant difference between a mapping electrode (which is directed to sensing) and an ablation electrode (which is configured to deliver ablation energy sufficient to ablate tissue). The only fair and reasonable reading of Kordis is that it teaches a mapping electrode, but not an ablation electrode. For at least these reasons, the 102 rejections of claims 1 and 19, and all claims that depend from them, should be withdrawn.

Additional Arguments to Support Patentability of Claims 3, 7, 8 and 9

Claims 3, 7, 8 and 9 are allowable for an additional and independent reason. Regarding claim 3, the Examiner alleges that Kordis discloses "at least one electrode compris[ing] at least one flexible and resilient (column 6, lines 9-11) electrode strand (elements 22, 92 and 96). Applicant respectfully disagrees. Element 22 of Kordis refers to "spline elements" which are completely distinct elements from the alleged electrode structure of Kordis. The passage cited by the Examiner actually recites that "the *spline elements* 22 comprise thin, rectilinear strips of resilient metal or plastic material." (column 6, lines 9-11). Applicant agrees that this section of Kordis describes a resilient member, but the member is the spline—which again is separate and distinct from the electrode element. Construction of the resilient spline elements is described in a separate section of the specification (see generally "Section A: The Support Assembly," column 6, line 46 – column 11, line 31; see also Figures 39 and 40 showing spline element 22 installed separately into the electrode structure). Figures 39 and 40, in particular, are especially helpful in explaining that spline 22 is an element separate from electrode 96. Thus, while Kordis may teach the use of a resilient spline 22, it does not teach the use of a resilient electrode 96.

Indeed, the Examiner seems to have implicitly recognized the limitations of Kordis in citing Section B of the specification, "The Electrode Assembly":

> "The electrode bands 96 and associated electrical connections ***bend virtually without generating stress*** during handling, manipulation, and use." (col. 12, lines 54-56).

Since bending the electrode bands does not generate stress, it necessarily follows that the electrode bands cannot generate the stress that is necessary to return the bands to their unbent configuration – which is the definition of resilience. Thus, the Examiner cites precisely the passage in Kordis that confirms the lack of resiliency in the electrode. As detailed above, and as cited by the Examiner, the resilience is found in the spline elements, not the electrodes.

Since Kordis does not teach at least one flexible and resilient electrode strand, as required by Applicant's claims, the rejection of claim 3 based on anticipation should be withdrawn for at least this additional and independent reason.

Similarly, claims 7-9 require an "elastically deformable" electrode strand. As discussed above, Kordis fails to disclose an electrode strand having any resiliency, and therefore, cannot possibly disclose an "elastically deformable" electrode strand. Thus, for at least the same reason that claim 3 is allowable, claims 7-9 are allowable.

Additional Argument to Support Patentability of Claim 5

Claim 5 is allowable for an additional and independent reason as well. The Examiner alleges Kordis discloses an ablation catheter wherein "the at least one electrode strand defines a saw tooth pattern (Fig. 35)." Office action at page 5. Applicant respectfully disagrees that Figure 35 comports with any understanding of a "saw tooth" pattern as it would be understood by one of skill in the art. Random House Unabridged Dictionary 2006: "having a zigzag profile, similar to that of the cutting edge of a saw." A comparison of Applicant's Figure 13 with Figure 35 of Kordis shows that there is a clear difference between the saw tooth pattern of Figure 13 and the pattern

depicted in Figure 35 of Kordis. Applicant respectfully suggests that Figure 35 of Kordis would represent an extremely "dull" saw – one that would not conform to any known definition of "saw tooth." The rejection based on anticipation should be withdrawn for at least this reason.

Additional Argument to Support Patentability of Claim 14:

Claim 14 is also allowable for an additional and independent reason. The Examiner alleges that Kordis discloses an "at least one electrode strand [ ] interlaced along the inside surface (Fig. 38 at the base of the loop structure)." Office action at page 6. Applicant submits that the Examiner may have misinterpreted Figure 38. As Applicant views Figure 38, there is no evidence that any of the alleged electrode strands found in Figure 38 are interlaced along the inside surface. At first blush, it appeared as if insulating sleeve 98 that is located at the center of the assembly may be located on an axis of the general spherical distal end, but a careful review of the drawing as a whole, reveals that insulating sleeve 98 is not on an axis, but rather is on a circumference of the sphere-like assembly. Only by virtue of a direct frontal view does it appear to be on an axis. Thus, the electrodes 96 are not on an inside surface at all, but rather an outer surface. Indeed, a reasonable reading of Kordis is that it teaches placing the mapping electrodes only on the outer surface because in order to map the electrical activity of tissue, you must place the mapping electrodes in contact with the tissue. Because Kordis does not disclose an electrode assembly with the electrode interlaced on the inside surface, the rejection of claim 14 should be withdrawn.

Rejections under 35 U.S.C. § 103(a) based on Kordis

Claims 17-18 stand rejected in the alternative as obvious over Kordis. Specifically, the Examiner alleges that Kordis discloses an ablation catheter and that "it would have been obvious to one of ordinary skill in the art . . . to have modified Kordis by increasing the length of electrodes E1-E8 and decreasing the space between these electrodes, thereby creating an even more generally exposed segment, in order to

expose a larger area of the electrodes and ablate more tissue at one time." (Office action at page 9). Regarding claim 18, the Examiner alleges it would have been obvious to "couple[ ] the electrode strand with a power supply in order to perform the desired function of the apparatus and ablate tissue." (Id.)

As noted above, Applicant amends claim 1 to more clearly recite that the ablation catheter includes an ablating electrode. Applicant also explains above that Kordis does not teach an ablating electrode as required by Applicant's claims. More particularly, and especially relevant to the 103 rejection, Kordis actually "teaches away" from spacing the electrodes more closely together as suggested by the Examiner. A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553, 31 U.S.P.Q.2D (BNA) 1130, 1131 (Fed. Cir. 1994). Although the impact of the recent Supreme Court case of KRS v. Teleflex, 550 U.S. ___ (2007), is still being assessed, the Court made clear that whether a reference "teaches away" from Applicant's claims remains a valid indicia of non-obviousness..

Applicant respectfully asserts that a fair reading of Kordis can only conclude that the electrode structure cited by the Examiner teaches away from ablation techniques in general and against spacing electrodes more contiguously in particular. As argued earlier, Kordis identifies safe and efficacious endocardial mapping techniques as its "principle objective." (Col. 2, lines 7-8). To meet that objective, Kordis recites:

> An endocardial mapping structure can potentially remain in place within a heart chamber for several thousand heart beats. During this time, the powerful contractions of heart muscle constantly flex and stress the structure. ***The structure must be strong and flexible enough to keep the electrodes spaced apart both longitudinally and circumferentially*** without failure and without shed parts. In addition, there is also the need to provide simple, yet reliable ways of electrically coupling multiple electrodes to external sensing equipment." (Kordis at col. 1, lines 57-65).

Ablation is a treatment technique that sometimes follows an initial mapping procedure. However, it is well known by those of skill in the art that the apparatus and techniques used in ablation and mapping are very different. Kordis explicitly recites that the structure of the mapping electrode "cage" is designed to keep the mapping electrodes separated in a manner that allows them to gather the maximum amount of electrical mapping information possible throughout an entire endocardial chamber. Indeed, the preferred embodiment cited by the Examiner in Figure 38 employs seven different splines all containing separately conducting electrode sets radiating out in a three-dimensional sphere. All other embodiments are similarly directed toward the objective of dispersing separate sets of mapping electrodes across as wide a three dimensional area as possible. The Kordis approach is entirely divergent from ablation procedures in general, and Applicant's claims in particular. As a mapping device, the electrodes must be electrically separate so that they can measure the electrical activity at different sites. To create "a generally continuously exposed segment of the at least one strand" as required by claim 17 would frustrate the purpose of measuring electrical activity at a plurality of locations. Thus, Kordis appears to teach away from Claim 17. For at least this reason, the alternative rejections based on obviousness should be withdrawn.

Conclusion

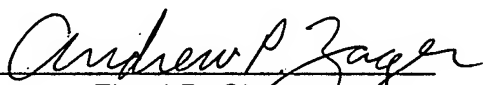
Applicant submits that the application is in condition for allowance. Timely notification of allowability is requested.

Applicant submits a two (2) month extension of time request along with the requisite fee. No additional fees, other petitions, additional claim fees, or any other fees are believed to be necessary to enter and consider this paper. If, however, any further extensions of time are required or any fees are due in order to enter or consider this paper or enter or consider any paper accompanying this paper, including fees for net addition of claims, Applicant hereby requests any extensions or petitions necessary and the Commissioner is hereby authorized to charge our Deposit Account No. 50-1129 for any fees. If there is any variance between the fee submitted and any fee required, or if the payment or fee payment information has been misplaced or is somehow insufficient to provide payment, the Commissioner is hereby authorized to charge or credit Deposit Account No. 50-1129.

Respectfully submitted,

WILEY REIN LLP

Date: May 14, 2007

By: 
Floyd B. Chapman
Registration No. 40,555
Andrew P. Zager
Registration No. 48,058

WILEY REIN LLP
Attn: Patent Administration
1776 K Street, N.W.
Washington, D.C. 20006
Telephone: 202.719.7000
Facsimile: 202.719.7049